REMARKS/ARGUMENTS

A formal request for interference accompanies this response. Applicants respond to the office action using the paragraph numbering of the office action. Support for the amendment to claim 35 is provided at p. 14, line 14. Support for new claims 64-67 is provided at e.g., p. 20, line 23.

4. Formal drawings are attached.

7. All claims stand rejected for alleged lack of enablement for reasons of record. Applicants have previously responded to the reasons of record in the previous and earlier responses, and it is believed that no purpose would be served by repeating these remarks in full. However, applicants attach a declaration by Dr. Baekkeskov that provides expert insight on some of these issues. Applicants also comment on the two newly cited references. Results reported for other diseases are less significant and do nothing to change the undisputed evidence that is directly applicable to insulin dependent diabetes. That is, treatment of GAD has been showed to induce tolerance in numerous independent studies on a NOD mouse model, and a phase II human clinical trial is currently in progress. Also, it is noted that the Examiner omits to mention parts of the articles that do not support his positions. For example, the Goodnow article reports that "substantial improvements" above baseline were observed in the Collerol trial and that Autoimmune still "firmly believes in its technology."

8-9. Claim 31 stands rejected as anticipated by US 5,762,937. Because the Examiner declines to say that he is not rejecting claim 31 over the claims of the '937 patent, and because no material difference between the claims is discerned, applicants assume that the rejection is made over the claims of the '937 patent, and accordingly request the issue be resolved by interference.

11-12. Claim 62 has been amended as suggested.

13-14. Claims 35 and 54-57 stand rejected as anticipated the US 4,086,142 (citing to col. 4, lines 14-16). This rejection is respectfully traversed.

Claim 35 is directed to a composition comprising glutamic acid decarboxylase in a pharmaceutically acceptable carrier for parenteral administration to a human patient. It is well known that such compositions must be *inter alia* sterile, substantially isotonic and made under conditions of good manufacturing practice to be administered to humans. For example, Remington's Pharmaceutical Sciences (cited at p. 21, line 4) in connection with preparation of parenteral compositions states at p. 1546 that

> An inherent requirement for parenteral preparations is they be of the very best quality and provide the maximum safety for the patient....Even the thought of using inferior techniques or ingredients in a manufacturing process must not be countenanced.

Here, the preparation discussed by the '142 patent is disclosed as being "crude" and dissolved in a buffer of 20 mM acetate and pH 5.5. This is a laboratory preparation suitable only for analytical use. The '142 patent does not disclose that the preparation was sterilized, dissolved in isotonic buffer, or otherwise prepared in accordance with good manufacturing practices. In these circumstances, it would have been, at the very least, grossly irresponsible, and probably, illegal to administer parenterally the preparation of the '142 patent to a human patient. Accordingly, '142 preparation cannot be considered to have been a pharmaceutical composition for parenteral administration to a human patient. Thus, there is no anticipation.

Further with respect to claim 54, the Examiner has not identified teaching in the '142 patent relating to lower molecular weight GAD.

15. Claims 35, 49 and 54-57 stand rejected as anticipated by the '947 patent. Again, the Examiner does not say whether he is rejecting the claims only over the specification or over the claims as well. Except with respect to claim 49 and 54 directed to lower molecular weight GAD, it is assumed that the rejection is based on the claims, and can be overcome only by interference. With respect to claims 49 and 54, the Examiner indicates that claim 1 of the '947 patent is directed to lower molecular weight GAD, and as lower molecular weight GAD is

the only GAD taught by the reference, there is anticipation. However, claim 1 makes no reference to lower molecular weight GAD. The Examiner has also failed to identify anywhere else in the '947 patent that that distinguishes between upper and lower molecular weight GAD, much less proposes using the lower molecular weight form for therapeutic methods. Therefore, the rejection should be withdrawn for claims 49 and 54.

16. It is believed that all claims were jointly owned by the University of California and Yale University at all relevant times.

17-18. Claims 34, 50-53 and 58-59 stand rejected as obvious over the '947 patent. Claim 34 has been cancelled. With respect to claims 50-53, the Examiner does not say whether he is rejecting the claims only over the specification or over the claims as well. It is assumed that the rejection is based on the claims, and can be overcome only by interference. With respect to claims 58 and 59, applicants note as above that no teaching has been identified in the '947 patent relating to lower molecular weight GAD.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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